

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,)	
DAIICHI SANKYO CO., LTD.,)	
DAIICHI SANKYO, INC.,)	
UBE INDUSTRIES, LTD.,)	
)	No. 1:14-cv-00389-SEB-TAB
Plaintiffs,)	
)	
vs.)	
)	
ACCORD HEALTHCARE INC., et al.)	
)	
Defendants.)	

SECOND ORDER ON DEFENDANTS' MOTION TO STAY

This cause is again open before the Court on a motion to stay [[Filing No. 349](#)]. Though fewer Defendants have requested a stay this time around, Defendants' arguments are more compelling. While the Court previously denied Defendants' motion to stay [[Filing No. 329](#)], for the reasons set forth below a stay is now appropriate.

Last time around, the Court found Defendants' request for stay to be premature in that no *inter partes* review had been instituted and thus there was no parallel proceeding that could address any of the issues in this litigation. [[Filing No. 329, at ECF p. 2.](#)] The Court therefore denied the stay request but did so without prejudice to Defendants renewing this request. On September 15, 2015, the United States Patent and Trademark Office issued orders instituting IPR of the '703 and '325 patents at issue in this case. This development is significant.

Stays are often favored in infringement suits involving co-pending reexamination of the patents-in-suit by the PTO. *Cook Inc. v. Endologix, Inc.*, 09-cv-1248, 2010 WL 325960, at *1 (S.D. Ind. Jan. 21, 2010) (citing cases). In deciding whether to exercise its discretion to stay the

litigation once an IPR has been instituted, the Court should consider whether a stay will: (1) simplify the issues and streamline the case for trial; (2) reduce the burden of litigation on the parties and the Court; and (3) unduly prejudice or tactically disadvantage the Plaintiff.

There is no question that the IPRs will streamline the case and narrow the issues for trial. As this Court has recognized, “it is virtually undeniable that a stay followed by a PTO reexamination will simplify the issues in the case and streamline the proceedings.” *Cook*, 2010 WL 325960, at *2 (quoting *Lincoln Nat’l Life Ins. Co. v. Transamerica Fin. Life Ins. Co.*, No. 08-cv-135, 2009 WL 1108822, at *4 (N.D. Ind. Apr. 24, 2009)). If Defendants are successful in the IPRs, all of the claims of the ‘703 and ‘325 patent will cease to exist and 22 parties will be entitled to judgment in their favor and dismissal.

Staying this litigation will avoid the possibility of obtaining a result that is inconsistent with any decision by the PTO involving the ‘703 and ‘325 patents. The IPR proceedings do not have to eliminate every issue in the case in order for a stay of the litigation to be entered. This Court has recognized that “the *potential reduction* in the number of claims, patents, and/or prior art references at issue before the Court should this case ever resume,” demonstrated that the case will be streamlined and a stay of the litigation should be entered. *Cook*, 2010 WL 325960, at *2 (emphasis added). The fact that IPR proceedings do not include all the patents asserted in the district court litigation “does not does eliminate the benefit of a stay in order to avoid duplicitous litigation on potentially moot claims and issues.” *Trading Techs., Int’l, Inc. v. BCG Partners, Inc.*, No. 10-715, 2015 WL 1396632, at *4 (N.D. Ill. Mar. 25, 2015). Regardless of the outcome of the IPRs, the issues in this case will be different and streamlined, and it would be prudent to stay this litigation so that the parties do not waste time and money developing a record for a case that is currently in flux.

In addition, a stay will reduce the burdens on the parties and the Court. This case is in its early stages, and a stay at this point will avoid wasted efforts. Plaintiffs and all Defendants except Lupin have engaged in minimal document and written discovery in this case (and very little additional discovery since Defendants' first motion to stay), no depositions have been noticed or taken, there are no dates for close of fact or expert discovery, the parties have not yet had a *Markman* hearing or opinion, and no trial date has been set. Lupin's case is truly in its infancy as a schedule has not even been entered. Thus, a stay will reduce the burdens on the parties and the Court.

The third factor to consider in deciding whether to issue a stay is whether a stay will unduly prejudice or tactically disadvantage Plaintiff. In previously addressing the issue of prejudice, the Court observed that the Hatch-Waxman Act provides for a stay of the FDA's approval of Defendants' ANDAs until June 2017; that this regulatory stay period was designed to give the Court an opportunity to address the merits of the patent suit prior to approval of Defendants' ANDA products; and that Defendants' motion to stay creates a very real possibility that this litigation would not be completed before the stay expires, or even before the '726 compound patent expires in April 2017. [[Filing No. 329, at ECF p. 2.](#)] Thus, the Court concluded, Defendants' requested stay unquestionably prejudices Plaintiffs.

Plaintiffs' chief concern on the issue of prejudice is that the case will be delayed such that it will not be resolved before the expiration of the statutory 30-month stay of approval of Defendants' ANDA provided for under the Hatch-Waxman Act. However, as Defendants' arguments conclusively demonstrate, Congress did not tie resolution of the patent litigation to approval of the product. [[Filing No. 350, at ECF pp.14-16](#); [Filing No. 357, at ECF pp.12-13.](#)] The fact that Plaintiffs cannot get final resolution of their case before the expiration of the 30-

month stay is not a recognized prejudice that can overcome the strong showing for a stay in this case. Plaintiffs will have ample opportunity to seek an injunction once the IPRs are finally concluded, which eliminates any alleged prejudice to Plaintiffs.

Plaintiffs argue that if the Court grants Defendants' request for a stay, the Court should order corresponding extension of the regulatory stay. [[Filing No. 355, at ECF p.17.](#)] There is no law that justifies this request. The only basis that courts have relied on to extend the regulatory stay is the violation of the statutory requirement of 21 U.S.C. § 355(j)(5)(B)(iii) that a party has failed to reasonably cooperate in expediting the litigation. There is no basis to make such a finding in this case. Therefore, the Court declines Plaintiffs' invitation to extend or toll the regulatory law stay.

Defendants make other arguments in support of their request for a stay. Perhaps most convincingly, Defendants quote Plaintiff Eli Lilly and Company's arguments from patent litigation arising out of the Eastern District of North Carolina in which Lilly made some of the same arguments Lilly now opposes. [[Filing No. 357, at ECF p. 4.](#)] Perhaps less persuasive, but also noteworthy, is Defendants' analogy of Lilly's litigation position to the Chicago Cubs' recent baseball season. [[Filing No. 357, at ECF pp. 13-14.](#)] Indeed, the parties' arguments are colorful and well crafted, leaving the Court with a difficult decision. However, for the reasons set forth, the Court grants Defendants' motion to stay¹. [[Filing No. 349](#)]. Accordingly, this action is stayed until the PTO issues a written decision regarding *inter partes* review of the '703 and '325 patents.

¹ The Court finds that oral argument would not likely contribute materially to resolution of the issues raised by these well-written briefs and therefore Defendants' joint motion for oral argument [[Filing No. 351](#)] is denied.

Date: 12/11/2015

A handwritten signature in black ink, appearing to read "T. Baker", written above a horizontal line.

Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

Distribution to all counsel of record via CM/ECF.